



DEPARTMENT OF THE AIR FORCE
59TH MEDICAL WING (AETC)
JOINT BASE SAN ANTONIO - LACKLAND TEXAS



22 JUNE 2017

MEMORANDUM FOR SGVT

ATTN: CAPT JOSEPH E MARCUS

FROM: 59 MDW/SGVU

SUBJECT: Professional Presentation Approval

1. Your paper, entitled **Diagnostic Evaluation of Military Blood Donors Screening Positive for Trypanosoma Cruzi Infection** presented at/published to **Medical Surveillance Monthly Report** in accordance with MDWI 41-108, has been approved and assigned local file #**17269**.
2. Pertinent biographic information (name of author(s) title, etc.) has been entered into our computer file. Please advise us (by phone or mail) that your presentation was given. At that time, we will need the date (month, day and year) along with the location of your presentation. It is important to update this information so that we can provide quality support for you, your department, and the Medical Center commander. This information is used to document the scholarly activities of our professional staff and students, which is an essential component of Wilford Hall Ambulatory Surgical Center (WHASC) internship and residency programs.
3. Please know that if you are a Graduate Health Sciences Education student and your department has told you they cannot fund your publication, the 59th Clinical Research Division may pay for your basic journal publishing charges (to include costs for tables and black and white photos). We cannot pay for reprints. If you are a 59 MDW staff member, we can forward your request for funds to the designated Wing POC at the Chief Scientist's Office, Ms. Alice Houy, office phone: 210-292-8029; email address: alice.houy.civ@mail.mil.
4. Congratulations, and thank you for your efforts and time. Your contributions are vital to the medical mission. We look forward to assisting you in your future publication/presentation efforts.

Linda Steel-Goodwin

LINDA STEEL-GOODWIN, Col, USAF, BSC
Director, Clinical Investigations & Research Support

PROCESSING OF PROFESSIONAL MEDICAL RESEARCH/TECHNICAL PUBLICATIONS/PRESENTATIONS

INSTRUCTIONS

USE ONLY THE MOST CURRENT 59 MDW FORM 3039 LOCATED ON AF E-PUBLISHING

1. The author must complete page two of this form:
 - a. In Section 2, add the funding source for your study [e.g., 59 MDW CRD Graduate Health Sciences Education (GHSE) (SG5 O&M); SG5 R&D; Tri-Service Nursing Research Program (TSNRP); Defense Medical Research & Development Program (DMRDP); NIH; Congressionally Directed Medical Research Program (CDMRP) ; Grants; etc.]
 - b. In Section 2, there may be funding available for journal costs, if your department is not paying for figures, tables or photographs for your publication. Please state "YES" or "NO" in Section 2 of the form, if you need publication funding support.
2. Print your name, rank/grade, sign and date the form in the author's signature block or use an electronic signature.
3. Attach a copy of the 59 MDW IRB or IACUC approval letter for the research related study. If this is a technical publication/presentation, state the type (e.g. case report, QA/QI study, program evaluation study, informational report/briefing, etc.) in the "Protocol Title" box.
4. Attach a copy of your abstract, paper, poster and other supporting documentation.
5. Save and forward, via email, the processing form and all supporting documentation to your unit commander, program director or immediate supervisor for review/approval.
6. On page 2, have either your unit commander, program director or immediate supervisor:
 - a. Print their name, rank/grade, title; sign and date the form in the approving authority's signature block or use an electronic signature.
7. Submit your completed form and all supporting documentation to the CRD for processing (59crdpubsres@us.af.mil). **This should be accomplished no later than 30 days before final clearance is required to publish/present your materials.** If you have any questions or concerns, please contact the 59 CRD/Publications and Presentations Section at 292-7141 for assistance.
8. The 59 CRD/Publications and Presentations Section will route the request form to clinical investigations, 502 ISG/JAC (Ethics Review) and Public Affairs (59 MDW/PA) for review and then forward you a final letter of approval or disapproval.
9. Once your manuscript, poster or presentation has been approved for a one-time public release, you may proceed with your publication or presentation submission activities, as stated on this form. **Note:** For each new release of medical research or technical information as a publication/presentation, a new 59 MDW Form 3039 must be submitted for review and approval.
10. If your manuscript is accepted for scientific publication, please contact the 59 CRD/Publications and Presentations Section at 292-7141. This information is reported to the 59 MDW/CC. All medical research or technical information publications/presentations must be reported to the Defense Technical Information Center (DITC). See 59 MDWI 41-108, *Presentation and Publication of Medical and Technical Papers*, for additional information.
11. The Joint Ethics Regulation (JER) DoD 5500.07-R, *Standards of Conduct*, provides standards of ethical conduct for all DoD personnel and their interactions with other non-DoD entities, organizations, societies, conferences, etc. Part of the Form 3039 review and approval process includes a legal ethics review to address any potential conflicts related to DoD personnel participating in non-DoD sponsored conferences, professional meetings, publication/presentation disclosures to domestic and foreign audiences, DoD personnel accepting non-DoD contributions, awards, honoraria, gifts, etc. The specific circumstances for your presentation will determine whether a legal review is necessary. **If you (as the author) or your supervisor check "NO" in block 17 of the Form 3039, your research or technical documents will not be forwarded to the 502 ISG/JAC legal office for an ethics review.** To assist you in making this decision about whether to request a legal review, the following examples are provided as a guideline:

For presentations before professional societies and like organizations, the 59 MDW Public Affairs Office (PAO) will provide the needed review to ensure proper disclaimers are included and the subject matter of the presentation does not create any cause for DoD concern.

If the sponsor of a conference or meeting is a DoD entity, an ethics review of your presentation is not required, since the DoD entity is responsible to obtain all approvals for the event.

If the sponsor of a conference or meeting is a non-DoD commercial entity or an entity seeking to do business with the government, then your presentation should have an ethics review.

If your travel is being paid for (in whole or in part) by a non-Federal entity (someone other than the government), a legal ethics review is needed. These requests for legal review should come through the 59 MDW Gifts and Grants Office to 502 ISG/JAC.

If you are receiving an honorarium or payment for speaking, a legal ethics review is required.

If you (as the author) or your supervisor check "YES" in block 17 of the Form 3039, your research or technical documents will be forwarded simultaneously to the 502 ISG/JAC legal office and PAO for review to help reduce turn-around time. If you have any questions regarding legal reviews, please contact the legal office at (210) 671-5795/3365, DSN 473.

NOTE: All abstracts, papers, posters, etc., should contain the following disclaimer statement:

"The views expressed are those of the [author(s)] [presenter(s)] and do not reflect the official views or policy of the Department of Defense or its Components"

NOTE: All abstracts, papers, posters, etc., should contain the following disclaimer statement for research involving humans:

"The voluntary, fully informed consent of the subjects used in this research was obtained as required by 32 CFR 219 and DODI 3216.02_AFI 40-402."

NOTE: All abstracts, papers, posters, etc., should contain the following disclaimer statement for research involving animals, as required by AFMAN 40-401_IP :

"The experiments reported herein were conducted according to the principles set forth in the National Institute of Health Publication No. 80-23, Guide for the Care and Use of Laboratory Animals and the Animal Welfare Act of 1966, as amended."

PROCESSING OF PROFESSIONAL MEDICAL RESEARCH/TECHNICAL PUBLICATIONS/PRESENTATIONS			
1. TO: CLINICAL RESEARCH	2. FROM: (Author's Name, Rank, Grade, Office Symbol) Joseph Marcus, O-3, 959 CSPS	3. GME/GHSE STUDENT: <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO	4. PROTOCOL NUMBER: FWH201700054N
5. PROTOCOL TITLE: (NOTE: For each new release of medical research or technical information as a publication/presentation, a new 59 MDW Form 3039 must be submitted for review and approval.) Follow up and outcomes of personnel screening positive for Chagas disease upon blood donation at JBSA-Lackland			
6. TITLE OF MATERIAL TO BE PUBLISHED OR PRESENTED: Diagnostic evaluation of military blood donors screening positive for Trypanosoma cruzi infection			
7. FUNDING RECEIVED FOR THIS STUDY? <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO FUNDING SOURCE:			
8. DO YOU NEED FUNDING SUPPORT FOR PUBLICATION PURPOSES: <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO			
9. IS THIS MATERIAL CLASSIFIED? <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO			
10. IS THIS MATERIAL SUBJECT TO ANY LEGAL RESTRICTIONS FOR PUBLICATION OR PRESENTATION THROUGH A COLLABORATIVE RESEARCH AND DEVELOPMENT AGREEMENT (CRADA), MATERIAL TRANSFER AGREEMENT (MTA), INTELLECTUAL PROPERTY RIGHTS AGREEMENT ETC.? <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO NOTE: If the answer is YES then attach a copy of the Agreement to the Publications/Presentations Request Form.			
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<input checked="" type="checkbox"/> 11a. PUBLICATION/JOURNAL (List intended publication/journal.) Medical Surveillance Monthly Report			
<input type="checkbox"/> 11b. PUBLISHED ABSTRACT (List intended journal.)			
<input type="checkbox"/> 11c. POSTER (To be demonstrated at meeting: name of meeting, city, state, and date of meeting.)			
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13. EXPECTED DATE WHEN YOU WILL NEED THE CRD TO SUBMIT YOUR CLEARED PRESENTATION/PUBLICATION TO DTIC NOTE: All publications/presentations are required to be placed in the Defense Technical Information Center (DTIC). DATE _____			
14. 59 MDW PRIMARY POINT OF CONTACT (Last Name, First Name, M.I., email) Marcus, Joseph E, joseph.e.marcus3.mil@mail.mil			15. DUTY PHONE/PAGER NUMBER 210-220-7072
16. AUTHORSHIP AND CO-AUTHOR(S) List in the order they will appear in the manuscript.			
LAST NAME, FIRST NAME AND M.I.	GRADE/RANK	SQUADRON/GROUP/OFFICE SYMBOL	INSTITUTION (If not 59 MDW)
a. Primary/Corresponding Author Marcus, Joseph E	Capt	959 CSPS	
b. Webber, Bryant J	Maj	559 Trainee Health Squadron	
c. Cropper, Thomas L		Trainee Health Surveillance	
d. Wilson, Matthew C	Maj	559 Trainee Health Squadron	
e. Yun, Heather C	LtCol	959 MDOS	
17. IS A 502 ISG/JAC ETHICS REVIEW REQUIRED (JER DOD 5500.07-R)? <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO			
I CERTIFY ANY HUMAN OR ANIMAL RESEARCH RELATED STUDIES WERE APPROVED AND PERFORMED IN STRICT ACCORDANCE WITH 32 CFR 219, AFMAN 40-401 JP, AND 59 MDWI 41-108. I HAVE READ THE FINAL VERSION OF THE ATTACHED MATERIAL AND CERTIFY THAT IT IS AN ACCURATE MANUSCRIPT FOR PUBLICATION AND/OR PRESENTATION.			
18. AUTHOR'S PRINTED NAME, RANK, GRADE Joseph E Marcus, Capt, USAF, MC	19. AUTHOR'S SIGNATURE MARCUS JOSEPH E 1410684892		20. DATE 20 JUN 2017
21. APPROVING AUTHORITY'S PRINTED NAME, RANK, TITLE Kristen R. Glass, Maj, USAF, MC	22. APPROVING AUTHORITY'S SIGNATURE GLASS KRISTEN R 1246687419		23. DATE 20 JUN 2017

PROCESSING OF PROFESSIONAL MEDICAL RESEARCH/TECHNICAL PUBLICATIONS/PRESENTATIONS			
1st ENDORSEMENT (59 MDW/SGVU Use Only)			
TO: Clinical Research Division 59 MDW/CRD Contact 292-7141 for email instructions.	24. DATE RECEIVED June 20, 2017	25. ASSIGNED PROCESSING REQUEST FILE NUMBER 17269	
26. DATE REVIEWED 21 Jun 2017		27. DATE FORWARDED TO 502 ISG/JAC	
28. AUTHOR CONTACTED FOR RECOMMENDED OR NECESSARY CHANGES: <input type="checkbox"/> NO <input checked="" type="checkbox"/> YES If yes, give date. <u>21 Jun 2017</u> <input type="checkbox"/> N/A			
29. COMMENTS <input checked="" type="checkbox"/> APPROVED <input type="checkbox"/> DISAPPROVED The author provided his research determination authorization. The abstract is approved.			
30. PRINTED NAME, RANK/GRADE, TITLE OF REVIEWER Rocky Calcote, PhD, Clinical Research Administrator		31. REVIEWER SIGNATURE CALCOTE ROCKY D. 1178245844 <small>Digitally signed by CALCOTE ROCKY D. 1178245844 DN: cn=Rocky D. Calcote, o=59 MDW, ou=CRD, email=rocky.calcote@59mdw.mil, c=US Date: 2017.06.22 09:13:41 -0500</small>	32. DATE June 22, 2017
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36. PRINTED NAME, RANK/GRADE, TITLE OF REVIEWER		37. REVIEWER SIGNATURE	38. DATE
3rd ENDORSEMENT (59 MDW/PA Use Only)			
39. DATE RECEIVED June 22, 2017		40. DATE FORWARDED TO 59 MDW/SGVU June 22, 2017	
41. COMMENTS <input checked="" type="checkbox"/> APPROVED (In compliance with security and policy review directives.) <input type="checkbox"/> DISAPPROVED			
42. PRINTED NAME, RANK/GRADE, TITLE OF REVIEWER Kevin Iinuma, SSgt/E-5, 59 MDW Public Affairs		43. REVIEWER SIGNATURE IINUMA KEVIN MITSUGU. 1296227 613 <small>Digitally signed by IINUMA KEVIN MITSUGU. 1296227 DN: cn=Kevin Mitsugu Iinuma, o=59 MDW, ou=Public Affairs, email=kevin.iinuma@59mdw.mil, c=US Date: 2017.06.22 09:30:48 -0500</small>	44. DATE June 22, 2017
4th ENDORSEMENT (59 MDW/SGVU Use Only)			
45. DATE RECEIVED		46. SENIOR AUTHOR NOTIFIED BY PHONE OF APPROVAL OR DISAPPROVAL <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> COULD NOT BE REACHED <input type="checkbox"/> LEFT MESSAGE	
47. COMMENTS <input type="checkbox"/> APPROVED <input type="checkbox"/> DISAPPROVED			
48. PRINTED NAME, RANK/GRADE, TITLE OF REVIEWER		49. REVIEWER SIGNATURE	50. DATE

59th Medical Wing (59th MDW)
Institutional Review Board (IRB)
59th Clinical Research Division/SGVUS/(210) 292-7143
2200 Bergquist Dr, Bldg 4430, Lackland AFB, TX 78236-5300

24 Feb 2017

FINAL DETERMINATION – NON-HUMAN RESEARCH

Determination Date: 24 Feb 2017

Project Lead: LTC Heather Yun/SG051

Reference Number: FWH20170054N

Project Title: Follow up and outcomes of personnel screening positive for Chagas disease upon blood donation at JBSA-Lackland

You may begin your project, as you would any other clinical or operational activity, with the approval and sponsorship of your leadership.

Your project was determined on 24 Feb 2017 to be considered **not human research** as defined by DoD regulation **32 CFR 219 and FDA regulation 21 CFR 56**. Continued IRB oversight for this activity is not required. The proposed project does not include non-routine intervention or interaction with a living individual for the primary purpose of obtaining data regarding the effect of the intervention or interaction, nor do the researchers obtain private, identifiable information about living individuals.

Since the IRB does not have regulatory oversight for your study, it is the investigator's responsibility to validate the study's scientific merit and research design and to ensure the conduct of the study is upheld by the highest ethical standards, as required by the Wing. Should you require assistance in reviewing the scientific merit and research design of your study, please contact the Protocol Office. Protection of subjects' rights safety and welfare and responsibility for protecting PHI/PII and research data now fall on the investigator and their commander.

In accord with DoDI 6000.08 any intramural funding of this study as research or as a clinical investigation may continue to be received or sought regardless of this IRB determination.

Your study has received a one-time research determination. If the goals and/or activities of the project change during the course of the project, or if new activities are proposed that would constitute human subjects research, re-contact the Protocol Office, so that a regulatory expert may determine whether or not the revised plan involves human subject research activities.

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Thomas Gibbons, PhD

Designated Exempt Reviewer

Diagnostic evaluation of military blood donors screening positive for *Trypanosoma cruzi* infection

Joseph E. Marcus, MD (Capt, USAF); Bryant J. Webber, MD, MPH (Maj, USAF); Thomas L. Cropper, DVM, MPVM; Matthew C. Wilson, DO (Maj, USAF); Heather C. Yun, MD (Lt Col, USAF)

Disclaimer

The views expressed are those of the authors and do not reflect the official views or policy of the Department of Defense and its Components.

Abstract

Routine blood donor screening for *Trypanosoma cruzi*, the causative parasitic agent of Chagas disease, began in the United States in 2007. Results of follow-up testing and evaluation after a positive screen have not been studied in the Armed Forces. Among first-time donors at the Joint Base San Antonio-Lackland Blood Bank between January 2014 and December 2016 (N=43,402), 23 (0.05%) screened positive for *T. cruzi*. This descriptive study highlights demographic and follow-up information for all 22 cases among active duty service members; a non-active duty member was excluded due to unavailability of clinical records. Members who screened positive received 13 different combinations of confirmatory testing (mean: 2.5 tests per person). In select cases, clinical evaluation included electrocardiogram (n=15) and 30-second rhythm and strip (n=5). Two patients met criteria for Chagas disease, 11 were considered negative, and nine were indeterminate. Among a small cohort of active duty service members who screened positive for *T. cruzi* infection on blood donation, diagnostic workup and evaluation varied considerably. Opportunities exist to decrease heterogeneity and improve evaluation of persons screening positive.